CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

206229Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

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Date of This Review:	December 2, 2014
Application Type and Number:	NDA 206229
Product Name and Strength:	Liletta (Levonorgestrel-releasing Intrauterine System) 52 mg
Product Type:	Drug-Device Combination Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Medicines 360
Submission Date:	October 3, 2014
Panorama #:	2014-39504
DMEPA Primary Reviewer:	Denise V. Baugh, PharmD, BCPS
DMEPA Associate Director:	Irene Z. Chan, PharmD, BCPS

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Liletta, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant submitted an external name study, conducted by (b) (4), for this product.

1.1 REGULATORY HISTORY

The sponsor previously submitted the proposed proprietary name (b) (4) on May 20, 2014. We found the proposed name, (b) (4) unacceptable due to (b) (4) as well as shared product characteristics with the proprietary name (b) (4) in OSE Review #2014-17369 dated August 6, 2014.

The sponsor submitted the name, Liletta, for review on October 3, 2014.

1.2 PRODUCT INFORMATION

We note that the Applicant has referred to their product as "Levonorgestrel-releasing Intrauterine (b) (4)" in their submission. After internal discussion with Chemicals, Manufacturing, and Controls (CMC), it was determined that the proper established name is "Levonorgestrel-releasing Intrauterine System".

The following product information is provided in the October 3, 2014 proprietary name submission.

- Intended Pronunciation: lye-LET-uh
- Active Ingredient: levonorgestrel
- Indication of Use: prevention of pregnancy for up to 3 years
- Route of Administration: vaginal
- Dosage Form: intrauterine device
- Strength: 52 mg which is released at the rate of 18.6 mcg per day. The rate decreases progressively after insertion while maintaining efficacy.
- Dose and Frequency: one device every 3 years; device may be removed at any time, but must be removed by the end of the third year.
- How Supplied: levonorgestrel-releasing intrauterine system is packaged together with an inserter in a peelable pouch and is available in a carton of one sterile unit
- Storage: Store at 20°C to 25°C (68°F to 77°F) with excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]. Protect from light until ready to use.

2 RESULTS

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Bone, Reproductive and Urologic Products (DBRUP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proprietary name[1].

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Liletta in their submission. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 FDA Name Simulation Studies

Ninety-two practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Forty-five (17 outpatient, 1 voice, and 27 inpatient) of the 92 participants correctly interpreted the proposed name as "Liletta".

Of the remaining 47 participants who misinterpreted the name, the most common misinterpretations occurred in the voice studies where 'tt' was interpreted for the letter 'd' (n = 6) or a single letter 't' (n = 21). Appendix B contains the results from the verbal and written prescription studies.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, October 23, 2014 e-mail, the Division of Bone, Reproductive, Urologic Products (DBRUP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.4 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names with the combined orthographic and phonetic score of ≥50% retrieved from our POCA search[2] organized as highly similar, moderately similar

[1]USAN stem search conducted on November 6, 2014.

or low similarity for further evaluation. There were no additional names identified from the external study conducted by (b) (4).

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score ≥70%	2
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	122
Low similarity name pair: combined match percentage score ≤49%	0

2.2.5 Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities

Our analysis of the 124 names contained in Table 1 determined all 124 names will not pose a risk for confusion as described in Appendices C through H.

2.2.6 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Bone, Reproductive and Urologic Products (DBRUP) via e-mail on November 18, 2014. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DBRUP on November 18, 2014, they stated no additional concerns with the proposed proprietary name, Liletta.

3 CONCLUSIONS

The proposed proprietary name, Liletta, is acceptable.

If you have further questions or need clarifications, please contact Shawnetta Jackson, OSE project manager, at 301-796-4952.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Liletta, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your October 3, 2014 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

[2] POCA search conducted on November 5, 2014.

4 REFERENCES

1. ***USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)***

   USAN Stems List contains all the recognized USAN stems.

2. ***Phonetic and Orthographic Computer Analysis (POCA)***

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html#).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. . For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNCE. OPDP or DNCE evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNCE provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [3]

[3] National Coordinating Council for Medication Error Reporting and Prevention. http://www nccmerp.org/aboutMedErrors html. Last accessed 10/11/2007.

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there medical and/or coined abbreviations in the proprietary name?**
	Proprietary names should not incorporate medical abbreviations (e.g., QD, BID, or others commonly used for prescription communication) or coined abbreviations that have no established meaning.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 50% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥50% to ≤ 69%.
- Low similarity: combined match percentage score ≤49%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names with overlapping or similar strengths or doses represent an area for concern for FDA. The dosage and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and it can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form, etc.) may be limited when the strength or dose overlaps. We review such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

   Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

   Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair do not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥50% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: o Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. o Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. o Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.

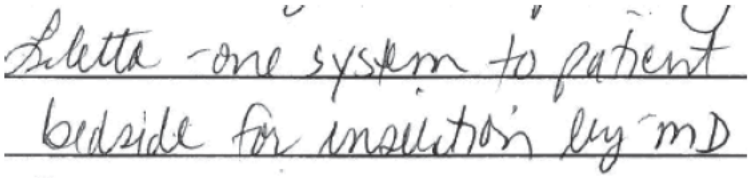
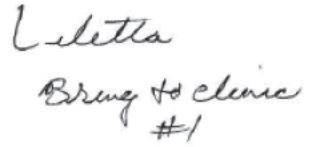
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤49%).

In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where, for example, there are data that suggest a name with low similarity is nonetheless misinterpreted as a marketed product name in a prescription simulation study. In such instances, FDA would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Liletta Study (Conducted on October 29, 2014)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order:  	"Liletta – bring to clinic, dispense # 1"
Outpatient Prescription:  	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

258 People Received Study
92 People Responded

Study Name: Liletta

OUTPATIENT	VOICE	INPATIENT
LELETTA (9)	LAILYTA (1)	LELETTA (2)
LIBETTA (1)	LALITA (1)	LIBETTA (2)
LILETLA (3)	LI-LITA (1)	LILETTA (27)
LILETTA (17)	LILEETA (1)	LILETTE (1)
LULETTA (1)	LILEIDA (1)	LOLETTA (1)
	LILETA (6)	
	LILETTA (1)	
	LILIDA (2)	
	LILITA (8)	
	LYLIDA (3)	
	LYLITA (2)	
	MYLITA (1)	

Appendix C: Highly Similar Names (e.g., combined POCA score is ≥70%)

No.	**Proposed name: Liletta** **Established name: levonorgestrel intrauterine system** **Dosage form: intrauterine device** **Strength(s): 52 mg** **Usual Dose: insert vaginally every 3 years**	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	Liletta	100	Name is the subject of this review.
2.	(b) (4)		

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥50% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Proposed Name	POCA Score (%)
1.	Levitra	61
2.	Levolet	60
3.	Alimta	58
4.	Celexa	58
5.	Latuda	58
6.	Lunesta	58
7.	Xeloda	57
8.	Dasetta 1/35	56
9.	Dasetta 7/7/7	56
10.	Inlyta	56
11.	Lessina-21	56
12.	Lessina-28	56
13.	Cylert	54

14.	Levo-T	54
15.	Lusedra	54
16.	Trileptal	54
17.	Zebeta	54
18.	Kaletra	53
19.	Levatol	52
20.	Lyrica	62
21.	Lioresal	51
22.	Veletri	51
23.	Vitekta	51
24.	Diabeta	50
25.	Lazanda	50
26.	Linzess	50
27.	Pletal	50
28.	(b) (4)	53
29.		50
30.	Lortab 10	52
31.	Zileuton	52
32.	Nalex-A	54
33.	Aceta	50
34.	Levotabs	50
35.	Lorab	52
36.	Ludent	52

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥50% to ≤69%) **with overlap** or numerical similarity in Strength and/or Dose

No.	**Proposed name: Liletta** **Established name: levonorgestrel intrauterine system** **Dosage form: intrauterine device** **Strength(s): 52 mg** **Usual Dose: insert vaginally every 3 years**	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	Lialda	68	The infixes of this name pair have sufficient orthographic differences. The second syllable of this name pair sounds different.
2.	Lysteda	58	The prefixes and infixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different.
3.	Trilyte	55	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first syllables of this name pair sound different. The proposed name, Liletta, has an additional syllable.
4.	Zylet	55	The prefixes of this name pair have sufficient orthographic differences. Additionally, the proposed name, Liletta is longer in length than the marketed name, Zylet (7 vs. 5 letters). The first syllable of this name pair sound different. The proposed name, Liletta has an additional syllable.
5.	Cyclessa	54	The prefixes/infixes/suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables have sufficient phonetic differences.
6.	Xalatan	54	The prefixes/infixes/suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables have sufficient phonetic differences.

No.	**Proposed name: Liletta** **Established name: levonorgestrel intrauterine system** **Dosage form: intrauterine device** **Strength(s): 52 mg** **Usual Dose: insert vaginally every 3 years**	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
7.	Levlite	53	The infixes and suffixes of this name pair have sufficient orthographic differences. The first syllables have sufficient phonetic differences. The proposed name, Liletta has an additional syllable.
8.	Brilinta	52	The prefixes/infixes of this name pair have sufficient orthographic differences. The first/second syllables have sufficient phonetic differences.
9.	Byetta	52	The prefixes of this name pair have sufficient orthographic differences. The first syllables have sufficient phonetic differences.
10.	Lente	52	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables have sufficient phonetic differences. The proposed name, Liletta has an additional syllable.
11.	Lidex	52	The infixes and suffixes of this name pair have sufficient orthographic differences. Additionally, the proposed name, Liletta is longer in length than the marketed name, Lidex (7 vs. 5 letters). The second syllables have sufficient phonetic differences. The proposed name, Liletta has an additional syllable.
12.	Lidex-E	52	The infixes and suffixes of this name pair have sufficient orthographic differences. The second syllables have sufficient phonetic differences. Additionally, the modifier 'E' help distinguish this name pair phonetically if included.
13.	Neulasta	52	The prefixes/infixes of this name pair have sufficient

No.	Proposed name: Liletta Established name: levonorgestrel intrauterine system Dosage form: intrauterine device Strength(s): 52 mg Usual Dose: insert vaginally every 3 years	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
			orthographic differences. The first and second syllables have sufficient phonetic differences.
14.	Loryna	51	The prefixes /infixes/suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables have sufficient phonetic differences.
15.	Lovaza	51	The infixes/suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables have sufficient phonetic differences.
16.	Alfenta	50	The prefixes/infixes of this name pair have sufficient orthographic differences. The first and second syllables have sufficient phonetic differences.
17.	Elestat	50	The prefixes/infixes/suffixes of this name pair have sufficient orthographic differences. The first/third syllables have sufficient phonetic differences.
18.	Elitek	50	The prefixes/infixes/suffixes of this name pair have sufficient orthographic differences. The first and third syllables have sufficient phonetic differences.
19.	Folicet	50	The prefixes/infixes/suffixes of this name pair have sufficient orthographic differences. The first and third syllables have sufficient phonetic differences.
20.	Gilenya	50	The prefixes/infixes/suffixes of this name pair have sufficient orthographic differences.

No.	**Proposed name: Liletta** **Established name: levonorgestrel intrauterine system** **Dosage form: intrauterine device** **Strength(s): 52 mg** **Usual Dose: insert vaginally every 3 years**	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
			The first, second, and third syllables have sufficient phonetic differences.
21.	Levora 0.15/30-21	50	The prefixes/infixes/suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables have sufficient phonetic differences.
22.	Levora 0.15/30-28	50	The prefixes/infixes/suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair have sufficient phonetic differences.
23.	Lexiva	50	The prefixes/infixes/suffixes of this name pair have sufficient orthographic differences. The first and second syllables have sufficient phonetic differences.
24.	Relenza	50	The prefixes/infixes/suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables have sufficient phonetic differences.
25.	Rilutek	50	The prefixes/infixes/suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables have sufficient phonetic differences.
26.	Tri-Luma	50	The prefixes/infixes/suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables have sufficient phonetic differences.
27.	(b) (4)	52	The prefixes and infixes of this name pair have sufficient orthographic differences.

No.	Proposed name: Liletta Established name: levonorgestrel intrauterine system Dosage form: intrauterine device Strength(s): 52 mg Usual Dose: insert vaginally every 3 years	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
			The first syllables of this name pair have sufficient phonetic differences. Additionally, the proposed name, Liletta has an additional syllable.
28.	(b) (4)	52	The suffixes of this name pair have sufficient orthographic differences. The first/third syllables of this name pair have sufficient phonetic differences.
29.		50	The prefixes/infixes of this name pair have sufficient orthographic differences. The first and second syllables have sufficient phonetic differences.
30.	Lemtrada***	50	The prefixes, infixes and suffixes of this name pair have sufficient orthographic differences. The first and second syllables have sufficient phonetic differences.
31.	(b) (4)	50	The prefixes, infixes and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables have sufficient phonetic differences.
32.		50	The infixes and suffixes of this name pair have sufficient orthographic differences. The first, second and third syllables have sufficient phonetic differences.
33.	Lessina	56	The prefixes, infixes and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables have sufficient phonetic differences.
34.	Levora	50	The prefixes, infixes and suffixes of this name pair have sufficient orthographic differences.

No.	**Proposed name: Liletta** **Established name: levonorgestrel intrauterine system** **Dosage form: intrauterine device** **Strength(s): 52 mg** **Usual Dose: insert vaginally every 3 years**	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
			The first, second, and third syllables have sufficient phonetic differences.
35.	Del-Beta	58	The prefixes/infixes of this name pair have sufficient orthographic differences. The first /second syllables of this name pair have sufficient phonetic differences.
36.	Saleto	58	The prefixes of this name pair have sufficient orthographic differences. The first syllables of this name pair have sufficient phonetic differences.
37.	Saleto-200	58	The prefixes of this name pair have sufficient orthographic differences. Additionally, the marketed name, Saleto-200 appears longer in length than the proposed name, Liletta when the modifier, '200' is included. The first syllables of this name pair have sufficient phonetic differences. Additionally, the inclusion of the modifier '200' will help distinguish this name pair when spoken.
38.	Solesta	57	The prefixes/infixes of this name pair have sufficient orthographic differences. The first/second syllables have sufficient phonetic differences.
39.	Levlen	56	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair have sufficient phonetic differences. Additionally, the proposed name, Liletta has an additional syllable.
40.	Lustra	54	The prefixes and infixes of this name pair have sufficient orthographic differences.

No.	Proposed name: Liletta Established name: levonorgestrel intrauterine system Dosage form: intrauterine device Strength(s): 52 mg Usual Dose: insert vaginally every 3 years	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
			The first and second syllables of this name pair have sufficient phonetic differences. Additionally, the proposed name, Liletta has an additional syllable.
41.	Nalex-A 12	54	The prefixes and suffixes of this name pair have sufficient orthographic differences. Additionally, the inclusion of the modifiers 'A' and '12' help to further differentiate this name pair. The first and second syllables of this name pair have sufficient phonetic differences. Additionally, the modifiers 'A' and '12' further differentiate this name pair when spoken.
42.	Lorcet	53	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair have sufficient phonetic differences. Additionally, the proposed name, Liletta has an additional syllable.
43.	Orlenta	53	The prefixes/infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair have sufficient phonetic differences.
44.	Cylate	52	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair have sufficient phonetic differences. Additionally, the proposed name, Liletta has an additional syllable.
45.	Jolivette	52	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair have sufficient phonetic differences.
46.	Levacet	52	The prefixes /infixes/suffixes of this name pair have

No.	Proposed name: Liletta Established name: levonorgestrel intrauterine system Dosage form: intrauterine device Strength(s): 52 mg Usual Dose: insert vaginally every 3 years	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
			sufficient orthographic differences. The first, second, and third syllables have sufficient phonetic differences.
47.	Relera	52	The prefixes /infixes/suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables have sufficient phonetic differences.
48.	Bellatal	51	The prefixes /infixes/suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables have sufficient phonetic differences.
49.	Sele-Pak	51	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first and third syllables have sufficient phonetic differences.
50.	Aler-Tab	50	The prefixes /infixes/suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables have sufficient phonetic differences.
51.	AllerTan	50	The prefixes /infixes/suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables have sufficient phonetic differences.
52.	Ilopan	50	The prefixes /infixes/suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables have sufficient phonetic differences.
53.	Lutera	50	The prefixes /infixes/suffixes of this name pair have sufficient orthographic differences.

No.	Proposed name: Liletta Established name: levonorgestrel intrauterine system Dosage form: intrauterine device Strength(s): 52 mg Usual Dose: insert vaginally every 3 years	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
			The first, second, and third syllables of this name pair have sufficient phonetic differences.
54.	Folitab	52	The suffixes of this name pair have sufficient orthographic differences. The third syllable of this name pair have sufficient phonetic differences. Name was found in Rx Norm. The marketed name, 'Folitab 500' was found in Redbook. Product characteristics were not found for 'Folitab' (without the modifier) in commonly used drug databases.
55.	(b) (4)	52	The infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair have sufficient phonetic differences. DMEPA found this proposed name to be acceptable (OSE Review # 2013-1242 dated October 10, 2013). No alternate proprietary names have been submitted by the Applicant.

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤49%)

No.	Name	POCA Score (%)
1.	N/A	

Appendix G: Names not likely to be confused or not used in usual practice settings for the reasons described.

No.	Name	POCA Score (%)	Failure preventions
1.	(b) (4)	56	Alternate name to Lupaneta Pack. NDA 203696 was approved December 14, 2012 with the proprietary name, Lupaneta Pack.
2.		55	Proposed name was found to be unacceptable (OSE Review # (b) (4) No alternate proprietary names have been submitted by the Applicant.
3.		54	The Applicant withdrew the proposed proprietary name, (b) (4) *** from consideration (b) (4)
4.		52	NDA 202872 was approved September 28, 2012 with the proprietary name, Lotemax.
5.		51	NDA 022458 was approved May 1, 2012 with the proprietary name, Elelyso.
6.		51	Name entered by Safety Evaluator. Product characteristics not found in commonly used drug database.
7.		50	Proposed proprietary name found to be unacceptable (OSE Review # 2010-354 dated May 4, 2010). NDA 022527 was approved September 21, 2010 with the proprietary name, Gilenya.
8.		50	NDA 022571 was approved July 28, 2010 under the proprietary name, Cuvposa.
9.		50	Alternate proposed proprietary name to Introvale***. DMEPA found the proprietary name, Introvale*** acceptable (OSE Review # 2008-1978 dated November 7, 2014) for ANDA 079064.

10.	(b) (4)	50	Proprietary name was found to be unacceptable (OSE Review # 2010-773 dated October 4, 2010) for IND 72177. NDA 203093 was approved September 24, 2014 with the proprietary name, Vitekta.
11.	Leventa	66	Name found in Rx Norm. Product characteristics not found in commonly used drug databases.
12.	Saleto-400	58	Name found in Rx Norm. Product characteristics not found in commonly used drug databases.
13.	Saleto-600	58	Name found in Rx Norm. Product characteristics not found in commonly used drug databases.
14.	Saleto-800	58	Name found in Rx Norm. Product characteristics not found in commonly used drug databases.
15.	Diltia	57	Name found in Rx Norm. Product characteristics not found in commonly used drug databases.
16.	Dilotab	56	Name found in Rx Norm. Product characteristics not found in commonly used drug databases.
17.	Xylitan	56	Name found in Rx Norm. Product characteristics not found in commonly used drug databases.
18.	Lerosett	56	Name found in Rx Norm. Product characteristics not found in commonly used drug databases.
19.	Leustat	53	Name found in Rx Norm. Product characteristics not found in commonly used drug databases.
20.	Legacy	52	Name found in Rx Norm. Product characteristics not found in commonly used drug databases.
21.	Livetan DM	52	Name found in Rx Norm. Product characteristics not found in commonly used drug databases.
22.	Lortab 0.5/33.3	52	Name found in Rx Norm. Product characteristics not found in commonly used drug databases.
23.	Replesta	52	Name is classified as a medical food (source: Redbook)
24.	Wilate	52	Name is classified as a blood product (source: Redbook)
25.	Balanta	51	Name found in Rx Norm. Product characteristics not found in commonly used drug databases.
26.	Libetist	51	Name found in Rx Norm. Product characteristics not found in commonly used drug databases.
27.	Gelato	50	Name found in Rx Norm. Product characteristics not found in commonly used drug databases.

28.	Linde	50	Name found in Rx Norm. Product characteristics not found in commonly used drug databases.
29.	Linoleate	50	Name found in Rx Norm. Product characteristics not found in commonly used drug databases.
30.	Lyclear	50	Name found in Rx Norm. Product characteristics not found in commonly used drug databases.
31.	Silapap	50	Name found in Rx Norm. The marketed names Silapap Children's and Silapap Infant are listed in Redbook and do not overlap in strength and/or dose with Liletta. Product characteristics for Silapap (without the modifier) were not found in commonly used drug databases.

Appendix H: Names not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name	POCA Score (%)
1.	N/A	

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/s/

DENISE V BAUGH
12/02/2014

IRENE Z CHAN
12/03/2014

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)

Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	August 6, 2014
Application Type and Number:	NDA 206229
Product Name and Strength:	(b) (4) (Levonorgestrel-releasing Intrauterine (b) (4) 52 mg
Product Type:	Drug- (b) (4) Combination Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Medicines 360
Submission Date:	May 20, 2014
Panorama #:	2014-17369
DMEPA Primary Reviewer:	Denise V. Baugh, PharmD, BCPS
DMEPA Acting Team Leader:	Tingting Gao, PharmD
DMEPA Associate Director:	Irene Z. Chan, PharmD, BCPS
DMEPA Acting Director:	Kellie Taylor, PharmD, MPH

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